K030606

APR 2 1 2003

Section 1 D: 510(k) Summary of Safety and Effectiveness for COULTER® LH 750 Body Fluids Application

1.0 General Information

Applicant Name and Address:	Beckman Coulter, Inc. Cellular Analysis Division 11800 SW 147 Avenue Miami, FL 33196-2500
Primary Contact:	Stan Sugrue, Ph.D. Senior Regulatory Affairs Specialist Telephone: (305) 380-4552 FAX: (305) 380-3618 E-mail: stan.sugrue@coulter.com
Date:	February 24, 2003
Device Trade Name(s):	COULTER® LH 750 Hematology Analyzer
Device Generic Name(s):	Automated differential cell counter
Device Classification:	The COULTER® LH 750 Hematology Analyzer is a Class II medical device.

2.0 Pre-amendment Predicate Method

The COULTER® LH 750 Body Fluids Application claims substantial equivalence to the pre-amendment predicate method for enumeration of WBCs and RBCs via manual cell count method in a counting chamber by a skilled competent technician.

FDA 510(k) Number(s): Not applicable

3.0 Device Description

The COULTER® LH 750 Body Fluids Application is an automated method for enumeration of RBCs and WBCs in body fluids on the COULTER LH 750 Hematology Analyzer, an automated hematology analyzer capable of supplying a complete blood cell analysis and includes a differential leukocyte cell count. The LH 750 also provides automated reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs).

4.0 Principle of Method:

The COULTER LH 750 Body Fluids Application is an automated method for enumeration of RBCs and WBCs in body fluids on the COULTER LH 750 Hematology Analyzer. The LH 750 utilizes the Coulter Principle for automatically enumerating and sizing blood cells. The analyzer uses a reagent system consisting of an isotonic diluent, lytic reagents to lyse the red cells without significantly affecting the white cells and an instrument cleaner.

5.0 Comparison to Predicate

Similarities/ Differences	Characteristic	Manual method (Predicate)	LH 750 Body Fluids Application
Similarities	Intended Use	To provide a quantitative determination of blood cells in cerebrospinal fluid, serous fluid, and synovial fluid	Same as manual method
	Specimen Analyzed	Body Fluids collected in a container with or without anti-coagulant	Same as manual method
Differences	WBC Count (cells/µL)	Manual cell count performed in a counting chamber by a skilled competent technician	Automated count
	RBC count (cells/µL)	Manual cell count performed in a counting chamber by a skilled competent technician	Automated count

6.0 Indications for Use:

The COULTER LH 750 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories.The LH 750 Body Fluids Application adds a quantitative, automated procedure for analyzing cerebrospinal fluid, serous fluid, and synovial fluid to the LH 750, providing enumeration of the WBCs and the RBCs.

7.0 Conclusion:

The COULTER LH 750 Body Fluids Application is substantially equivalent to the manual microscopic predicate method for enumeration of RBCs and WBCs in body fluids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 1 2003

Stan Sugrue, Ph.D.
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 S.W. 147 Avenue
P.O. Box 169015
Miami, FL 33116-9015

Re: k030606
Trade/Device Name: COULTER® LH 750 Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: April 2, 2003
Received: April 3, 2003

Dear Dr. Sugrue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Section 1C: INDICATIONS FOR USE

510(k) Number (if known): ~~Not assigned~~ K030606

Device: COULTER® LH 750 Hematology Analyzer

Indications For Use:

The COULTER® LH 750 Hematology Analyzer is a quantitative, automated hematology Analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER® LH 750 Hematology Analyzer also provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs). The system also provides an automated method for enumeration of RBCs and WBCs in body fluids.

Future commercialization will add ISOTON® 4 diluent /Lyse S® 4 Lytic reagent to the indications for use.

21 CFR 864.5220 Automated differential cell counter

An automated differential cell counter is a device used to identify and classify one or more of the formed elements of blood.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices K030606
510(k) Number